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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/657,011	09/05/2003	Ann M. Maloney	10/041-2-C2	1738

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EXAMINER

FUBARA, BLESSING M

ART UNIT	PAPER NUMBER
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1618

DATE MAILED: 05/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/657,011	Applicant(s) MALONEY, ANN	
	Examiner Blessing M. Fubara	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 January 2005.
2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 50-54 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 50-54 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

James M. Spear
JAMES M. SPEAR
PRIMARY EXAMINER

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____

A4 1618

DETAILED ACTION

Examiner acknowledges receipt of request for extension of time, amendment and remarks filed 01/03/05. New claims 50-54 are pending.

Claim Rejections - 35 USC § 112

1. The rejection of claim 45 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in light of the cancellation of the claim.

Claim Rejections - 35 USC § 102

2. The rejection of claims 44 and 46-49 under 35 U.S.C. 102(e) as being anticipated by Eichman (US 5,980,882) is withdrawn because of the cancellation of claims 44 and 46-49.

Claim Rejections - 35 USC § 103

3. The rejection of claim 45 under 35 U.S.C. 103(a) as being unpatentable over Eichman (US 5,980,882) in view of Chow et al. (US 4,160,827) is withdrawn in light of the cancellation of claim 45.

However, the new claims presented give rise to new grounds of rejection.

4. Claims 50-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chow et al. (US 4,859,461).

Chow discloses a composition that comprises AMBERLITE-70 and pharmaceutically active basic drugs selected from dextromethorphan, codeine, hydrocodone, morphine and propranolol and an impregnating agent selected from hydroxypropylmethyl cellulose, hydroxypropyl cellulose, sorbitol, hydroxypropyl sorbitol, and polyvinylpyrrolidone for a prolonged continuous release of the active drugs. Chow further discloses that the hydroxyl alkyl

Art Unit: 1618

celluloses are present in amounts ranging from about 3% to about 20% and that the polyvinylpyrrolidone are present in amounts ranging from 7% to 20%. See column 1, lines 36-58 and column 2, lines 12-63. The particle size of the resin is from about 25 μm to about 1,000 μm (column 2, lines 53-57). A point in the particle size range of from about 25 μm to about 1000 μm reads on 50 μm . There is no demonstration that the amount of the resin recited in claim 50 provides unusual results. Chow does not disclose the amount of the drug that is bound to the resin. However, differences in amounts or concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such amount or concentration is critical. And “[w]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare the hydrocodone containing composition of Chow. One having ordinary skill in the art would have the know how to determine how much drug is needed for incorporation with the resin and the cellulose impregnating agent with the expectation having the desired drug dissolution profile.

5. Claims 50 and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chow et al. (US 4,859,461) in view of applicants admitted prior art.

Chow is described above. Chow’s drug-resin does not include phenolic amine resin. Examples of phenolic amine resins are AMBERLITE IRP-58 (applicants’ specification at paragraph [0027] of the published application # 20040062812). Applicants are aware that IRP-58 and IRP-69 are equivalent and as a teaching reference IRP-69 and IRP-70 are equivalent

Art Unit: 1618

(Eichman, US 5,980,882, column 6, lines 45-48). It would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare hydrocodone-containing formulation and to substitute IRP-70 with IRP-58 with the expectation of producing analgesic formulation.

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

7. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicants' cooperation is requested in correcting any errors of which applicants may become aware in the specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

Art Unit: 1618

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

BF

Blessing Fubara
Patent Examiner
Tech. Center 1600

James M. Spear

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